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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,431	02/13/2002	Klaus Unsicker	MBP-007 XX	2347

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,431	UNSICKER ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a preliminary amendment, filed 2/13/2002, that comprises an English translation of claims amended 8/17/2001 in the international application of which this application is the U.S. National Stage application (PCT/EP00/04445). Claims 1-26 are pending in the instant application and are subject to the following restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 23 and 25, drawn to pharmaceutical compositions comprising a nucleic acid or nucleic acid vector containing a nucleotide sequence encoding the primary amino acid sequence of a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group II, claim(s) 1-14, 23 and 25, drawn to pharmaceutical compositions comprising a protein encoded by a nucleic acid or nucleic acid vector containing a nucleotide sequence encoding the primary amino acid sequence of a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group III, claim(s) 1-14, 23 and 25, drawn to a pharmaceutical composition comprising an antibody, or functional fragment thereof, that binds a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group IV, claim(s) 1-14, 23 and 25, drawn to a pharmaceutical composition comprising an antagonist of a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group V, claim(s) 1-14, 23 and 25, drawn to a pharmaceutical composition comprising an agonist of a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group VI, claim(s) 15-22, 24 and 26, drawn to a diagnostic kit comprising a nucleic acid or nucleic acid vector containing a nucleotide sequence encoding the primary amino acid sequence of a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group VII, claim(s) 15-22, 24 and 26, drawn to a diagnostic kit comprising a protein encoded by a nucleic acid or nucleic acid vector containing a nucleotide sequence encoding the primary amino acid sequence of a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

Group VIII, claim(s) 15-22, 24 and 26, drawn to a diagnostic kit comprising an antibody, or functional fragment thereof, that binds a protein containing the 7 Cys-knot region of the TFG-B superfamily, or a functionally active derivative or part thereof, having at least a neurotrophic effect on dopaminergic neurons, wherein the gene coding for the protein is transcribed and/or translated in neurons and glial cells.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I is not novel in the art and is thus not a contribution over the prior art. PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The "special technical feature" of Group I is a nucleic acid encoding a protein comprising the 7 Cysteine-knot region of the TGF-B superfamily, or derivative or part thereof,

where the gene encoding the protein is expressed in neurons and glial cells and where the nucleic acid is comprised with a composition intended for use in the prevention and/or treatment of neurodegenerative disorders in mammals. Peulve et al teach methods of treating neurodegenerative disorders with nucleic acids encoding neurotrophic factors such as GDNF (glial cell derived neurotrophic factor) (U.S. 2002/0071828 A1, which claims priority to PCT/FR98/00595, which international application was published on 10/1/1998; see, for example, claims 6, 10, 13 and 14). Johnson et al teach that although GDNF is less than 20% identical to any other member of the TGF-B family, it contains the 7 cysteine residues which are conserved across the entire family and believed to be the basis of a conserved cysteine knot structure observed in the crystal structure determination of TGF-B2 (U.S. Patent No. 5,739,307 A; e.g. columns 37-38, bridging paragraph). Johnson et al further teach neurturin, a protein that also contains these 7 cysteine residues, but like GDNF is less than 20% homologous to any other member of the TGF-B family. Johnson et al teach nucleic acid compositions for the treatment of neurodegenerative disorders comprising nucleic acids that encode neurturin (e.g. column 5, lines 19-27). Thus, the special technical feature of Group I lacks novelty of inventive step and does not make a contribution over the prior art.

As the special technical feature of Group I lacks novelty, the inventions of Groups II-VIII do not form a single general inventive concept and instead are composed of the inventions outlined above. The technical feature of the remaining groups are different from Group I and each other in that they feature the structural/functional properties of different functional molecules as follows: a 7 Cys-knot protein (Groups II and VII), an antibody against a 7 Cys-knot protein (Groups III and VIII), an antagonist of a 7 Cys-knot protein (Group IV) and an antagonist

of a 7 Cys-knot protein (Group V). Further, the products of Groups I-V have a different composition and function from those of Groups VI-VIII (i.e. pharmaceutical compositions versus diagnostic kits).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

GERRY LEFFERS
PRIMARY EXAMINER